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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, LOUISE Z	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/740,694	ARIMILLI ET AL.	
	Examiner	Art Unit	
	Louise Wang, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-180* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, in part, 29-33, 61-65, 92-96, and 122-125, drawn to method for identifying a candidate compound as a suitable pro-drug, comprising contacting the candidate compound with a catalyst having carboxylic ester hydrolase activity to produce a metabolite compound; and identifying the candidate compound as a suitable pro-drug if the metabolite compound has a phosphonic acid group instead of the esterified phosphonate group of the candidate compound, or a carboxylic acid group instead of the esterified carboxyl group of the candidate compound, classified in class 435, subclass 19.

II. Claims 4-8, 34-40, 66-71, and 97-101, drawn to the method of providing a candidate compound by substituting a prototype compound with an esterified phosphonate or carboxyl group, classified in class 435, subclass 135.

III. Claims 9-11, 41-43,72-74, 102-104, and 144-147, in part, drawn to the method of determining the intracellular persistence of the candidate compound and the metabolite compound, classified in class 435, subclass 7.2.

IV. Claims 12-14, 44-46, 75-77, 105-107, 179, and 180, drawn to the method of determining the tissue selectivity of the candidate compound and the metabolite compound, classified in class 435, subclass 4.

V. Claims 15, 16, 47, 48, 78, 79, 108, 109, 148-151, 156-159, and 144-147, 152-155, and 169-172, in part, drawn to the method of determining the anti-HIV protease activity of the candidate and metabolite compound, classified in class 435, subclass 4.

VI. Claims 17-19, 49-51, 80-82, 110-112, 168, and 169, drawn to the method of determining the resistance of HIV to the candidate and metabolite compound, classified in class 435, subclass 4.

VII. Claims 20-28, 52-60, 83-91, 113-121, and 173-178, drawn to the method of determining the intracellular residence time of the candidate compound and the metabolite compound, classified in class 435, subclass 7.21.

VIII. Claims 126-129, drawn to a candidate compound that is an amino acid phosphonoamidate in which a carboxyl group of the amino acid is esterified, classified in class 435, subclass 135.

IX. Claims 130-137, drawn to a candidate compound that is substituted with an amino acid group in which a carboxyl group of the amino acid is esterified, classified in class 435, subclass 135.

X. Claims 138-143, drawn to a candidate compound wherein the esterified phosphonate group is mono-substituted with a hydroxyorganic acid linked

to the phosphorus atom through an oxygen atom, classified in class 435, subclass 135.

XI. Claims 152-155 and 169-172, in part, and 160-163, drawn to the method of determining the inhibition activity against HIV integrase of the candidate and metabolite compound, classified in class 435, subclass 4.

XII. Claims 152-155 and 169-172, in part, and 164-167, drawn to the method of determining the inhibition activity against HIV reverse transcriptase of the candidate and metabolite compound, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and (VIII-X) are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed esterification process in Group II can be used to make other and materially different product such as perfume or coupling a chemical to the surface of a solid resin.

Inventions (VIII-X) and (I, III-VII, XI, XII) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as screening for anti-cancer or other anti-viral drugs.

Inventions VIII-X are different products with respect to chemical structures and properties; therefore each product is patentably distinct.

Inventions I –VII, XI, and XII are different methods with respect to starting materials, physiological mechanisms, protocol procedures, and end products; therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and require non-coextensive literature and sequence searches even though in some cases the classification is shared, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Elections

This application contains claims directed to the following patentably distinct species of the claimed invention:

Should Applicant elect Group I, Application is additionally required to elect an experimental environment as exemplified by claims 29-32.

Should Applicant elect Group V, Application is additionally required to elect an assay environment as exemplified by claims 23-27.

These species are distinct because their structures, components, and physiological properties are different; thus, each represents patentably distinct subject matter. Furthermore, the examination of these species would require different searches in the scientific literature, which would not be coextensive. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. §121 to (1) elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable; and (2) list all claims readable thereon including those subsequently added.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Remarks

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

"Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Wang, Ph.D.
Patent Examiner
15 November 2005

JEFFREY STUCKER
PRIMARY EXAMINER